Applicants submit that the claims are not indefinite with respect to the term "matrix" or "solid matrix" and that the specification does clearly indicate the relationship between the matrix and the drug.

The term "matrix" is not defined in the specification, and does not need to be, because it is used in the common understanding of that term. The American Heritage Dictionary (Second College Edition, 1982) defines "matrix" first and foremost as "A situation or surrounding substance within which something originates, develops or is contained." That is what is meant by the terms "matrix" and "solid matrix" in this application - a (solid) surrounding substance within which something (a drug) is contained.

Thus, just as examples, the specification states:

"The invention in these embodiments is a single dosage form for oral administration that includes both a solid-state drug dispersed or otherwise retained in a solid matrix of a water-soluble polymer...."(p. 6 lines 26-28) (emphasis added)

"This invention further resides in pharmaceutical compositions containing a drug retained in a solid matrix ...." (p. 7 lines 31-32) (emphasis added)

The claims thus clearly define a composition in which a the solid matrix does not compose the drug but the drug is contained in a sold matrix. In addition, the claims call for the solid matrix being large enough when in the stomach to promote retention of itself in the stomach during the fed mode. Thos skilled in the art would know that were the solid matrix only the drug itself, administration of such a drug in a particle large enough to be retained in the stomach during the fed mode would mean that the drug was administered in a huge dose, totally unacceptable under medical practices. Therefore those skilled in the art would not consider that the current claims define pharmaceutical compositions in which the drug that is administered is itself the solid matrix.

As stated above, and as stated in the claims, the drug is contained in the solid matrix, and this would be understood from the generally accepted definition of the

term "matrix". Applicants respectfully request withdrawal of the rejection of claims under Section 112 as indefinite.

Claims 1 and 14-18 are rejected as anticipated by MacKenzie et al. The reason given is that MacKenzie et al discloses the reduction of body weight/mass in individuals receiving docusates and that the specification does not indicate whether the drug is in the solid matrix or the solid matrix is composed of the drug.

Applicants again state that the specification and the claims clearly state that the drug is contained in the solid matrix and does not compose the matrix. Additionally, MacKenzie et al. do not disclose administration of a fed mode inducing agent such as docusate together with any drug, but only disclose toxicological tests for docusate. MacKenzie et al. thus does not anticipate the current claims, nor does it render them obvious.

Withdrawal of the rejection of claims as anticipated by MacKenzie et al. is respectfully requested.

Claims 1 and 14-18 stand rejected as anticipated by Kais et al. The examiner takes the position that relieving constipation induces at least a degree of fed mode within the scope of the instant claims.

Applicants beg to differ. The fed mode is induced by activity in the stomach, not by relieving constipation much farther along the digestive tract. If the examiner maintains this position she is respectfully requested to provide documentation in support.

The medication in Kais et al is aimed at the use of docusate as a laxative. As explained earlier in the prosecution of this application, for instance in the response mailed July 30, 2003, the docusate's known function is to serve as a stool softener, and to perform that function it must be present in an effective amount in the colon. As is known in the art the docusate could be administered orally or as a suppository, but that does not matter - it must be administered so that there will be an effective amount of it in the colon; otherwise it will not perform the stool softening or laxative function.

Applicants submit that this position was accepted by the previous examiner as shown by the allowance of claims in the Office Action of November 6, 2003, over references disclosing the administration of laxative preparations containing docusate. In accordance with MPEP 706.04, the examiner is respectfully requested to continue this position.

Finally, claims 1 and 14-18 are rejected as obvious over the combination of WO 97/47285 with MacKenzie et al. Applicants again submit that with one reference being concerned with administration of drugs and the other concerned with testing docusate for toxicological effects, there is no basis whatever to combine the two in connection with claims that call for both a drug and docusate as well as the drug being contained in a solid matrix. As stated above the claims and specification state that the drug is in the matrix, not that the matrix is composed of the drug. Withdrawal of this rejection is thus respectfully requested.

## CONCLUSION

In view of the foregoing, Applicants Micheline Markey, John W. Shell, Bret Berner.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned.

Respectfully submitted,

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